Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0720027	10/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Capitol Medical Enterprises Llc Dba Capital Med Gr	8401 Connecticut Ave Ste 201, Chevy Chase, MD	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that the testing personnel (TP) and laboratory director (LD) attested to the routine integration of the samples into the patient workload using the laboratory's routine methods in six of six PT events reviewed. Findings: 1. The laboratory was enrolled in PT with American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) in modules for 1) Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG), 2) Severe acute respiratory virus coronavirus 2 molecular (SARS CoV-2), 3) Influenza type A and B and respiratory syncytial virus antigen (Flu A & B/RSV), and 4) hematology. 2. Records from the third event (M3) in 2023 to the second event (M2) in 2025 were reviewed for a total of six events. 3. Attestations and signatures were missing as follows: a. AAB-MLE M2 2025 i. CT/NG: the LD signature was missing ii. SARS CoV-2: the LD signature was missing iii. Flu A & B/RSV: the LD signature was missing iv. Hematology: the attestation form was missing b. AAB-MLE M1 2025 i. CT/NG: the LD and TP signatures were missing ii. SARS CoV-2: the attestation form was missing iii. Flu A & B/RSV: the LD and TP signatures were missing iv. Hematology: the attestation form was missing c. AAB-MLE M3 2024 i. CT/NG: the TP signatures were missing and the LD name was typed, but there was no signature ii. SARS CoV-2: the LD and TP signatures were missing iii. Flu A & B/RSV: the attestation form was missing iv. Hematology: the attestation form was missing d. AAB-MLE M2 2024 i. CT/NG: the LD name was typed, but there was no signature ii. SARS CoV-2: the TP signatures were missing and the LD name was typed, but there

	was no signature iii. Flu A & B/RSV: the LD name was typed, but there was no signature iv. Hematology: the LD signature was missing e. AAB-MLE M1 2024 i. CT /NG: the TP signatures were missing and the LD name was typed, but there was no signature ii. SARS CoV-2: the TP signatures were missing and the LD name was typed, but there was no signature iii. Flu A & B/RSV: the TP signatures were missing and the LD name was typed, but there was no signature iv. Hematology: the attestation form was missing f. AAB-MLE M3 2023 i. All attestation forms were missing 4. During the survey on 09/23/2025 at 12:58 PM, the TC confirmed that attestations were either missing or not signed by the LD and/or TP in six of six PT events reviewed.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the "Quality Assessment Program" procedure (QA procedure), proficiency testing (PT) records, and the PT provider's website, and interview with the technical consultant (TC), the laboratory failed to investigate all unacceptable PT results in three of six hematology PT events reviewed. Findings: 1. The QA procedure stated that "PT failures are investigated within 30 days and remedial action is taken." 2. The laboratory was enrolled in hematology PT modules with American Associate of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE). Records for the third event (M3) in 2023 through the second event (M2) of 2025 were reviewed for a total of six events. 3. AAB-MLE M3 2023 a. The laboratory received a score of 0% for hemoglobin. The laboratory also received a score of 0% for leukocytes and the three-part differential because results were not reported to the PT agency. b. There was no documentation of an investigation into the unacceptable results. 4. AAB-MLE M2 2024 a. The laboratory received a score of 80% for neutrophil (%) and lymphocyte (%) and a sore of 20% for monocyte (%). b. There was no documentation of an investigation into the unacceptable results. 5. AAB-MLE M1 2025 a. The laboratory received a score of 80% for leukocytes, eosinophil (%), and basophil (%); 60 % for neutrophil (%) and lymphocyte (%); and 20% for monocyte (%). b. The findings stated "Repeated out of range samples. All repeated values were [within] range except for the 2 lymph values" and that the issue "will resolve as this is probably an operator error." c. The investigation didn't specifically state which analytes were unacceptable and were repeated. There was no documentation of the repeat values for neutrophil (%), eosinophil (%), or basophil (%). d. The investigation didn't address whether patient samples had the potential to be affected or what corrective actions were taken to avoid the "operator error" in subsequent PT events. e. The AAB-MLE website listed the target evaluation date as 03/21/2025. The date of the investigation was 06/04 /2025, more than 30 days after the evaluation report was available as required by the procedure. 6. During the exit interview on 09/23/2025 at 4:00 PM, the TC confirmed that investigations into unacceptable PT results were either incomplete or not performed for three of six hematology PT events reviewed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by

	the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual (SOPM) and interview with the technical consultant (TC), the laboratory did not have approved pre-analytic, analytic, and post-analytic procedures for performing microbiology testing on the Cepheid GeneXpert system. Findings: 1. The laboratory performed microbiology testing using the Cepheid GeneXpert system. 2. The approved SOPM did not include any pre-analytic, analytic, and post-analytic procedures for the testing performed on the Cepheid GeneXpert system. 3. During the exit interview on 09/23/2025 at 4:00 PM, the TC confirmed that there were no approved procedures for performing testing using the Cepheid GeneXpert system.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory records and email communication with the technical consultant (TC), the laboratory failed to monitor the temperature and humidity in the room where testing was performed using the Cepheid GeneXpert system. Findings: 1. The operator manual for the Cepheid GeneXpert system listed the following operational environmental requirements: a. Temperature: 15-30 degrees Celsius b. Relative humidity: 10%-95% 2. In an email received on 10/03/2025 at 7:14 PM, the TC confirmed that the temperature and humidity was not monitored in the room where testing was performed using the Cepheid GeneXpert system.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: *This is a repeat deficiency. The laboratory was cited during the recertification survey completed on 09/21/2023 for not documenting maintenance activities for the Cepheid GeneXpert instruments. The laboratory's plan of correction stated this would be corrected by 11/30/2023. Based on review of maintenance records, and email and interview with the technical consultant (TC), the laboratory failed to ensure that maintenance activities for the Cepheid GeneXpert instruments were consistently

	documented as performed. Findings: 1. The laboratory performed microbiology testing using two Cepheid GeneXpert instruments: serial numbers 838806 and 11000347. In an email received on 10/03/2025 at 7:14 PM, the TC confirmed that testing was put on hold beginning in 05/2025 on serial number 11000347 due to low testing volume. 2. Maintenance records for the GeneXpert instruments were reviewed from 01/2024-08/2025. 3. A new maintenance form was implemented in 03/2025 which included two weekly and four quarterly maintenance activities. The second of the weekly and the fourth of the quarterly activities were never documented as performed. There was no approved procedure manual for the Cepheid GeneXpert system available at the time of the survey that explained each maintenance activity (cross-refer to tag D5401 for details) and the TC was unsure if the maintenance activities were applicable to the GeneXpert system used by the laboratory. 4. Monthly maintenance was either not performed or partially performed in four of 20 months reviewed for instrument 838806 (01/2024, 04/2024, 06/2024, and 08/2025). 5. Monthly maintenance was either not performed or partially performed in two of 14 months reviewed for instrument 11000347 (01/2024 and 06/2024). 6. Quarterly maintenance activities were not performed from 01/2024-09/2024 for either instrument. 7. During the exit interview on 09/23/2025 at 4:00 PM, the TC confirmed that maintenance activities for the Cepheid GeneXpert instruments were not consistently documented as performed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: I. Based on review of quality control (QC) records and email communication with the technical consultant (TC), the laboratory did not have an individualized quality control plan (IQCP) to reduce the frequency of performing QC for the microbiology testing performed on the Cepheid GeneXpert system. Findings: 1. The laboratory performed QC for microbiology testing performed on the Cepheid GeneXpert system monthly and with every new lot number. 2. In an email received on 10/03/2025 at 7: 14 PM, the TC confirmed that the laboratory did not have an IQCP to reduce the frequency of performing QC for microbiology testing performed on the Cepheid GeneXpert system from daily to monthly and with every new lot number. II. Based on review of quality control (QC) records and email communication with the technical consultant (TC), the laboratory failed to perform monthly QC on both Cepheid GeneXpert instruments for all four microbiology cartridge systems. Findings: 1. The laboratory performed microbiology testing using two Cepheid GeneXpert instruments: serial numbers 838806 and 11000347. In an email received on 10/03/2025 at 7:14 PM, the TC confirmed that testing was put on hold beginning in 05/2025 on serial number 11000347 due to low testing volume. 2. The laboratory did not have an individualized quality control plan (cross-refer to D5445 I above for more details) but

	performed QC for microbiology testing monthly and with every new lot number. 3. Four cartridge systems were used with the GeneXpert instruments: 1) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), 2) Streptococcus pyogenes group A, 3) Chlamydia trachomatis and Neisseria gonorrhoeae (CT/NG), and 4) a respiratory virus 4-plex (SARS-Cov-2/influenza A & B/respiratory syncytial virus). 4. GeneXpert QC records were reviewed for 01/2025-09/2025. 5. Records showed that QC was not performed for the SARS-CoV-2 and CT/NG cartridge systems on instrument 11000347 for the months of 01/2025-04/2025. 6. In the email received on 10/03/2025 at 7:14 PM, the TC confirmed that all four cartridge systems were run on both instruments for patient testing.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory director failed to ensure that the laboratory was enrolled in PT for Streptococcus pyogenes group A (Strep A) testing performed on the moderate complexity Cepheid GeneXpert system. Findings: 1. The laboratory performed Strep A testing on throat swabs using the moderate complexity Cepheid GeneXpert system. 2. The PT records for six events from the 2023 third event to the 2025 second event were reviewed and none of the PT modules included Strep A. 3. During the exit interview on 09/23/2025 at 4:00 PM, the TC confirmed that the laboratory was not enrolled in PT for Strep A.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of personnel records and email communication with the technical consultant (TC), the laboratory director failed to ensure that there were records of initial training for eight of 12 testing personnel (TP). Findings: 1. The Laboratory Personnel Report (form CMS-209) listed 12 TP. 2. Eight of the 12 TP were either newly hired employees or employees that had competency assessments from 2024, but no competency assessments prior to the previous recertification survey (09/21 /2023). 3. There were no records of initial training for the eight TP (TP# 1, 2, 6, 8, 9, 10, 11, and 12). 4. In an email received on 10/03/2025 at 7:14 PM, the TC confirmed that the laboratory "did not have initial training records for the Nursing/Lab personnel."
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)

	(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the standard operating procedure manual, the laboratory director failed to ensure that approved procedures for performing microbiology testing on the Cepheid GeneXpert system were available to the testing personnel. Cross-refer to tag D5401 for details.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the TC failed to ensure that the laboratory was enrolled in PT for Strep A testing. Cross-refer to tag D6015 for details.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of quality control (QC) records and interview with the technical consultant (TC), the TC failed to ensure that the laboratory had an individualized quality control plan to reduce frequency of QC performed for the Cepheid GeneXpert testing and failed to ensure that QC was tested for all cartridge systems on both GeneXpert instruments where patient testing was performed. Cross-refer to tag D5445 I and II.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the technical consultant (TC), the records did not include assessment of competency in performing microbiology testing on the Cepheid GeneXpert system. Findings: 1. The laboratory

	performed moderate complexity hematology and microbiology testing. 2. Records from 2024 only documented competency assessments for hematology testing and not for microbiology testing for all testing personnel. Competency had not been performed yet for 2025. 3. During the survey on 09/23/2025 at 3:50 PM, the TC confirmed that competency assessments performed in 2024 only included hematology testing and not microbiology testing.